K093057

BIOMET TRAUMA

DEC - 1 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter: Biomet Trauma
100 Interpace Parkway
Parsippany, NJ 07054

Establishment Registration Number: 2242816

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Regulatory Affairs Project Manager
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Date Prepared: October 29, 2009

Trade/Proprietary Name: Biomet® Vision® Foot Ring System

Common/Usual Name: External Fixation Device

Classification Name: Single/multiple metallic bone fixation appliances and accessories (21 CFR 888.3030)

Device Panel/Product Code: Orthopedics KTT

Device Description:
The Biomet® Vision® Foot Ring System was cleared in premarket notifications K071395 and K052239.

Indications for Use:
The indications for use for this system have been modified. The Biomet® Vision® Foot Ring System is intended for use in the treatment of bone conditions including leg

lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation treatment modality.

Additional indications for this system include:

- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

The Biomet Vision FootRing System is substantially equivalent to other legally marketed devices, including the Stryker Hoffman II Foot Ring (cleared under premarket notification K041706), and the SBi RingFIX™ System (cleared under premarket notification K071394).

Operational principles for the device are unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Biomet Trauma
% Ms. Margaret Crowe
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

DEC - 1 2009

Re: K093057
Trade/Device Name: Biomet® Vision® Foot Ring System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: November 20, 2009
Received: November 23, 2009

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093057

Device Name: Biomet® Vision® Foot Ring System

The Biomet® Vision® Foot Ring System is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation treatment modality.

Additional indications include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Temperature

Janette Z for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093057